

MAY 14 2014

K141010
Page 1 of 5

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: _____.

1. Submitter:

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Contact Person:

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Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: February 19, 2014

2. Device Name: M9/M9T/M9CV Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

M9/M9T/M9CV is a software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, Color-Mode, Power/Dirpower Mode, THI, iScape mode, Color M, Elastography, LVO or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color).

This system is a Track 3 device that employs an array of probes that include linear array and convex array with a frequency range of approximately 3.0 MHz to 10.0

B-1

005-1

MHz.

4. Intended Use:

The M9/M9CV/M9T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, trans-esoph.(Cardiac), peripheral vessel , urology exams.

5. Comparison with Predicate Devices:

M9/M9T/M9CV Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

| Predicate Device | Manufacturer | Model | 510(k) Control Number |
|------------------|--------------|------------|-----------------------|
| 1 | Mindray | DC-8 | K132341 |
| 2 | Mindray | M7 | K131690 |
| 3 | GE | Voluson E8 | K101236 |

M9/M9T/M9CV has the same technological characteristics, is comparable in key safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate devices. All systems transmit ultrasonic energy into patients and perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

- Subject device M9/M9T/M9CV has the same intended uses as the predicated device DC-8(K132341)

| Subject Device M9/M9T/M9CV | Predicate device DC-8 (K132341) |
|--|--|
| The M9/M9CV/M9T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, trans-esoph.(Cardiac), peripheral vessel , urology exams. | The DC-8/DC-8 PRO/DC-8 CV/DC-8 EXP/DC-8S diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac adult, cardiac pediatric, peripheral vessel, urology and transesophageal (Cardiac) exams. |

- All of the patient contact material of the M9/M9T/M9CV are the same as that of the predicated device DC-8(K132341) and the predicated device M7(K131690) with the exception of the materials for probe SP5-1s. Materials for the SP5-1s are tested under ISO 10993-1 for its biocompatibility.
- The acoustic power levels of M9/M9T/M9CV are below the limits of FDA, which is the same as the predicated device DC-8(K132341).
- M9/M9T/M9CV is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device DC-8(K132341).
- M9/M9T/M9CV has the same imaging modes as the predicated device DC-8(K132341): B, M, Color Doppler, PWD, CWD, Amplitude Doppler, Color M, Anatomical M Mode and combined mode).
- M9/M9T/M9CV has some special functions: iScape, TDI, TDI QA, LVO, Elastography, Stress Echo, Tissue Tracking QA, iWorks, iNeedle and IMT. All of them are identical as the predicated device DC-8(K132341).
- M9/M9T/M9CV has the same capacity in term of making comments and body marks on the images, reporting patient exam results as the predicated device DC-8(K132341).
- M9/M9T/M9CV has similar probes as the predicated device DC-8(K132341) and M7(K131690):

| Subject device M9/M9T/M9CV | Predicated device DC-8(K132341) | Predicated device M7(K131690) | NOTE |
|-------------------------------|------------------------------------|----------------------------------|---|
| C5-1s | C5-2E | / | They have same indications for use, mode of operation, array elements. Different design is intended to improve penetrability and spacial resolution. C5-1s probe has been tested under the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37. Differences do not influence the safety and effectiveness of this probe. |
| L12-4s | / | L12-4s | Same. |
| P10-4s | P10-4E | / | Same (except for the shape of the socket which does not affect the performance of the probe). |
| P7-3Ts | / | P7-3Ts | Same. |

| | | | |
|---------|-----------------|---------|--|
| L14-6Ns | / | L14-6Ns | Same. |
| V11-3Ws | V11-3WE | / | Same (except for the shape of the socket which does not affect the performance of the probe). |
| C11-3s | C11-3E | / | Same (except for the shape of the socket which does not affect the performance of the probe). |
| CW2s | CW2s | / | Same. |
| CW5s | CW5s | / | Same. |
| SP5-1s | P4-2NE P4-2E | / | SP5-1s has the same indications for use and performance specification with P4-2NE, except that indications for use Neonatal Cephalic is substantially equivalent to P4-2E. |

- M9/M9T/M9CV has the same measurement and calculation functions as the predicated device DC-8(K132341) except for the cardiac measurement and calculation MV ALL which is equivalent to predicated device Voluson E8(101236).

6. Non-clinical Tests:

M9/M9T/M9CV Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
- UD 3 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AAMI / ANSI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- IEC 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- ISO14971 Medical devices - Application of risk management to medical devices
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and

testing within a risk management process

- IEC 62366 Medical devices - Application of usability engineering to medical devices
- IEC 62304 Medical device software - Software life cycle processes

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

7. Clinical Studies

Not applicable. The subject of this submission, M9/M9T/M9CV Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the M9/M9T/M9CV Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 14, 2014

Shenzhen Mindray Bio-Medical Electronics, Co. Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K141010

Trade/Device Name: M9 Diagnostic Ultrasound System, M9T Diagnostic Ultrasound System, M9CV Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: April 24, 2014

Received: April 25, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the M9 Diagnostic Ultrasound System, M9T Diagnostic Ultrasound System, M9CV Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

C11-3s
P7-3Ts
L14-6Ns
CW5s

C5-1s
SP5-1s
V11-3Ws

L12-4s
P10-4s
CW2s

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141010

Device Name

M9/M9T/M9CV

Indications for Use (Describe)

The M9/M9CV/M9T Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), adult and pediatric cardiac, trans-esoph.(Cardiac), peripheral vessel , urology exams.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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008-2

Diagnostic Ultrasound Indications For Use Format

System: M9/M9T Diagnostic Ultrasound System

Transducer: N/A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|------------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | N | N | N | | N | N | N | Note 1, 2,4,5 |
| | Abdominal | N | N | N | N | N | N | N | Note 1, 2,4,5 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | N | N | N | N | Note 1, 2,4,5 |
| | Small Organ (Specify**) | N | N | N | | N | N | N | Note 1,2,5,6 |
| | Neonatal Cephalic | N | N | N | N | N | N | N | Note 1,2,4,5 |
| | Adult Cephalic | N | N | N | N | N | N | N | Note 1, 2,4,5 |
| | Trans-rectal | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Trans-vaginal | N | N | N | | N | N | N | Note 1, 2,4,5 |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Musculo-skeletal (Superficial) | N | N | N | | N | N | N | Note 1,2,5 |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | N | N | N | N | N | N | N | Note 1,2,3,4,5,7 |
| | Cardiac Pediatric | N | N | N | N | N | N | N | Note 1,2,3,4,5 |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | N | N | N | N | N | N | N | Note 1, 3,4 |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Other (Specify***) | N | N | N | | N | N | N | Note 1,2,4,5 |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: M9/M9T Diagnostic Ultrasound System

Transducer: C11-3s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Other (Specify***) | | | | | | | | |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

008-4

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System: M9/M9T Diagnostic Ultrasound System

Transducer: C5-1s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|----------------------|-----------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Abdominal | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Other (Specify***) | | | | | | | | |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

008-5

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System: M9/M9T Diagnostic Ultrasound System

Transducer: L12-4s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | P | P | P | | P | P | P | Note 1,2,5 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | P | P | P | | P | P | P | Note 1,2,5 |
| | Small Organ (Specify**) | P | P | P | | P | P | P | Note 1,2,5,6 |
| | Neonatal Cephalic | P | P | P | | P | P | P | Note 1,2,5 |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | P | P | P | | P | P | P | Note 1,2,5 |
| | Musculo-skeletal (Superficial) | P | P | P | | P | P | P | Note 1,2,5 |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | P | P | P | | P | P | P | Note 1,2,5 |
| | Other (Specify***) | | | | | | | | |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

008-6

System: M9/M9T Diagnostic Ultrasound System

Transducer: P7-3Ts

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | P | P | P | P | P | P | P | Note 1, 3, 4 |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | | | | | | | | |
| | Other (Specify***) | | | | | | | | |

N=new indication: P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

008-7

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System: M9/M9T Diagnostic Ultrasound System

Transducer: SP5-1s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|------------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | N | N | N | N | N | N | N | Note 1,2,4,5 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | N | N | N | N | Note 1,2,4,5 |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | N | N | N | N | Note 1,2,4,5 |
| | Adult Cephalic | N | N | N | N | N | N | N | Note 1,2,4,5 |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | N | N | N | N | N | N | N | Note 1,2,3,4,5,7 |
| | Cardiac Pediatric | N | N | N | N | N | N | N | Note 1,2,3,4,5 |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | | | | | | | | |
| | Other (Specify***) | | | | | | | | |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

008-8

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System: M9/M9T Diagnostic Ultrasound System

Transducer: P10-4s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | N | N | N | N | N | N | N | Note 1,4 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | N | N | N | N | N | N | N | Note 1,4 |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | N | N | N | N | N | N | N | Note 1,4 |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | N | N | N | N | N | N | N | Note 1, 3,4 |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | | | | | | | | |
| | Other (Specify***) | | | | | | | | |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4:Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: M9/M9T Diagnostic Ultrasound System

Transducer: L14-6Ns

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | P | P | P | | P | P | P | Note 1,2,5 |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | P | P | P | | P | P | P | Note 1,2,5 |
| | Small Organ (Specify**) | P | P | P | | P | P | P | Note 1,2,5,6 |
| | Neonatal Cephalic | P | P | P | | P | P | P | Note 1,2,5 |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | P | P | P | | P | P | P | Note 1,2,5 |
| | Musculo-skeletal (Superficial) | P | P | P | | P | P | P | Note 1,2,5 |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | P | P | P | | P | P | P | Note 1,2,5 |
| | Other (Specify***) | | | | | | | | |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

008-10

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System: M9/M9T Diagnostic Ultrasound System

Transducer: V11-3Ws

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Abdominal | | | | | | | | |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | N | N | N | | N | N | N | Note 1,2,4,5 |
| | Trans-vaginal | N | N | N | | N | N | N | Note 1, 2,4,5 |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| Cardiac | Intravascular | | | | | | | | |
| | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| Peripheral vessel | Intra-cardiac | | | | | | | | |
| | Peripheral vessel | | | | | | | | |
| | Other (Specify***) | N | N | N | | N | N | N | Note 1,2,4,5 |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3: TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: M9/M9T Diagnostic Ultrasound System

Transducer: CW2s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|-------------------|--------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | P | | | | |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | P | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | | | | P | | | | |
| | Cardiac Pediatric | | | | P | | | | |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | | | | P | | | | |
| | Other (Specify***) | | | | | | | | |

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

System: M9/M9T Diagnostic Ultrasound System

Transducer: CW5s

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | | Mode of Operation | | | | | | | |
|------------------------------|------------------------------------|-------------------|---|-----|-----|------------------|----------------------|-----------------------|-----------------|
| General (Track 1 Only) | Specific (Track 1 & 3) | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Combined (specify) | Other (specify) |
| Ophthalmic | Ophthalmic | | | | | | | | |
| Fetal Imaging & Other | Fetal | | | | | | | | |
| | Abdominal | | | | | | | | |
| | Intra-operative (Specify*) | | | | | | | | |
| | Intra-operative (Neuro) | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | P | | | | |
| | Small Organ (Specify**) | | | | | | | | |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph. (non-Card.) | | | | | | | | |
| | Musculo-skeletal (Conventional) | | | | | | | | |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| Cardiac | Cardiac Adult | | | | | | | | |
| | Cardiac Pediatric | | | | P | | | | |
| | Intravascular (Cardiac) | | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| Peripheral vessel | Peripheral vessel | | | | | | | | |
| | Other (Specify***) | | | | | | | | |

N=new indication: P=previously cleared by FDA: E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular.

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: iScape

Note 3:TDI

Note 4: Color M

Note5: Biopsy Guidance

Note6: Elastography

Note7: Contrast imaging (Contrast agent for LVO)

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)